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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,327	09/03/99	ROBERTSON S	A20-005

HM22/1127

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EXAMINER	
HUYNH,P	
ART UNIT	**PAPER NUMBER**
1644	4

DATE MAILED: 11/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/380,327	ROBERTSON ET AL.	
	Examiner	Art Unit	
	" Neon" Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *50-97* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. Applicant's preliminary amendment, filed on Sept/3/99 (Paper No. 3), is acknowledged.
Claims 1-49 have been canceled.
Claims 50-97 have been added.
Claims 50-97 are pending and being acted upon presently.

3. Applicant is advised that should claim 64 be found allowable, claim 65 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Election/Restrictions

4. The following is noted:

Independent claim 50 encompasses a method of treating an infertility condition in human or mammal which employs one or more antigens, one or more routes of administration, temporal of administration, one or more sites of administration, different forms of TGFβ, wherein antigen is:

A) MHC Class I Leukocyte antigen of prospective father,

B) Sperm antigen of prospective father, or

C) Antigen on the conceptus.

And wherein the form of TGFβ is:

A) Active form of TGFβ1,

B) Active form of TGFβ2,

C) Active form of TGFβ3,

D) Active TGFβ analogue including substitution, deletion, addition, peptide fragment,

E) Active form of Activin,

F) Inactive form of TGFβ1 plus platelets that activates TGFβ1,

G) Inactive form of TGFβ2 plus platelets that activates TGFβ2,

H) Inactive form of TGFβ3 plus platelets that activates TGFβ3,

I) Inactive form of TGFβ analogue plus platelets that activates TGFβ analogue, or

J) Inactive form of Activin plus plasmin that activates Activin.

Given the complexity of the method which use one or more antigens, various forms of TGFβ, TGFβ derivative or analog thereof, and different route and timing of administration, a person of ordinary skill in the art would not envision one in view of the other. In addition, TGFβ, TGFβ derivative or analog thereof and antigens differ with respect to their structure, biochemical properties and their mode of action.

Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

5. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this Action, to elect a single invention to which the claims must be restricted:

I. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 62, 63, 66, 67, 68, 69, 70, 71, 72, 73, 74, 79, 81, 83, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering of a prospective mother:
A) MHC Class I leukocyte antigen of prospective father
B) Active TGFβ1
classified in Class 424, subclass 85.1, Class 424, subclass 520.

II. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 62, 63, 66, 67, 70, 71, 72, 73, 76, 77, 79, 81, 83, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:
A) MHC Class I leukocyte antigen of prospective father
B) Active TGFβ2

classified in Class 424, subclass 85.1, Class 424, subclass 520.

III. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 62, 63, 66, 67, 70, 71, 72, 73, 76, 77, 79, 81, 83, 84, 85, 86, 87, 88, 90 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) MHC Class I leukocyte antigen of prospective father

B) Active TGFβ3

classified in Class 424, subclass 85.1, Class 424, subclass 520.

IV. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 62, 63, 66, 67, 70, 71, 72, 75, 76, 77, 79, 81, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) MHC Class I leukocyte antigen of prospective father

B) Active TGFβ analog

classified in Class 424, subclass 85.1, Class 424, subclass 520.

V. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 62, 63, 66, 67, 70, 71, 72, 78, 79, 81, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) MHC Class I leukocyte antigen of prospective father

B) Active activin

classified in Class 424, subclass 85.1, Class 424, subclass 520.

VI. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 62, 63, 66, 67, 68, 69, 70, 71, 72, 80, 82, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) MHC Class I leukocyte antigen of prospective father

B) Precursor TGFβ1 plus platelets

classified in Class 424, subclass 85.1, Class 424, subclass 520.

VII. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 62, 63, 66, 67, 70, 71, 72, 80, 82, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or human or mammal by administering a prospective mother:

A) MHC Class I leukocyte antigen of prospective father

B) Precursor TGFβ2 plus platelets

classified in Class 424, subclass 85.1, Class 424, subclass 520.

VIII. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 62, 63, 66, 67, 70, 71, 72, 80, 82, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or human or mammal by administering a prospective mother:

A) MHC Class I leukocyte antigen of prospective father

B) Precursor TGFβ3 plus platelets

classified in Class 424, subclass 85.1, Class 424, subclass 520.

IX. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 62, 63, 66, 67, 70, 71, 72, 75, 76, 77, 80, 82, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) MHC Class I leukocyte antigen of prospective father

B) Precursor TGFβ analog plus platelets

classified in Class 424, subclass 85.1, Class 424, subclass 520.

X. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 62, 63, 66, 67, 70, 71, 72, 78, 80, 82, 83, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or human or mammal by administering a prospective mother:

A) MHC Class I leukocyte antigen of prospective father

B) Precursor activin plus plasmin

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XI. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 64, 65, 66, 67, 68, 69, 70, 71, 73, 74, 79, 81, 83, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Sperm antigen of prospective father

B) Active TGFβ1

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XII. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 64, 65, 66, 67, 70, 71, 73, 76, 77, 79, 81, 83, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in human or mammal by administering a prospective mother:

A) Sperm antigen of prospective father

B) Active TGFβ2

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XIII. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 64, 65, 66, 67, 70, 71, 73, 76, 77, 79, 81, 83, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Sperm antigen of prospective father

B) Active TGFβ3

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XIV. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 64, 65, 66, 67, 70, 71, 75, 76, 77, 79, 81, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Sperm antigen of prospective father

B) Active TGFβ analog

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XV. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 64, 65, 66, 67, 70, 71, 78, 79, 81, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Sperm antigen of prospective father

B) Active activin

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XVI. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 64, 65, 66, 67, 68, 69, 70, 71, 80, 82, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Sperm antigen of prospective father

B) Precursor TGFβ1 plus platelets

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XVII. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 64, 65, 66, 67, 70, 71, 80, 82, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Sperm antigen of prospective father

B) Precursor TGFβ2 plus platelets

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XVIII. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 64, 65, 66, 67, 70, 71, 80, 82, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Sperm antigen of prospective father

B) Precursor TGFβ3 plus platelets

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XIX. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 64, 65, 66, 67, 70, 71, 75, 76, 77, 80, 82, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in human or mammal by administering a prospective mother:

A) Sperm antigen of prospective father

B) Precursor TGFβ analog plus platelets

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XX. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 64, 65, 66, 67, 70, 71, 78, 80, 82, 83, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Sperm antigen of prospective father

B) Precursor activin plus plasmin

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XXI. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 66, 67, 68, 69, 70, 73, 74, 79, 81, 83, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Antigen on the conceptus

B) Active TGFβ1

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XXII. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 66, 67, 70, 73, 76, 77, 79, 81, 83, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Antigen on the conceptus

B) Active TGFβ2

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XXIII. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 66, 67, 70, 73, 76, 77, 79, 81, 83, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Antigen on the conceptus

B) Active TGFβ3

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XXIV. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 66, 67, 70, 75, 76, 77, 79, 81, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Antigen on the conceptus

B) Active TGFβ analog

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XXV. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 66, 67, 70, 78, 79, 81, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Antigen on the conceptus

B) Active activin

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XXVI. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 66, 67, 68, 69, 70, 80, 82, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Antigen on the conceptus

B) Precursor TGFβ1 plus platelets

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XXVII. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 66, 67, 70, 80, 82, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Antigen on the conceptus

B) Precursor TGFβ2 plus platelets

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XXVIII. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 66, 67, 70, 80, 82, 84, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Antigen on the conceptus

B) Precursor TGFβ3 plus platelets

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XXIX. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 66, 67, 70, 75, 76, 77, 80, 82, 85, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Antigen on the conceptus

B) Precursor TGFβ analog plus platelets

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XXX. Claims 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 66, 67, 70, 78, 80, 82, 83, 86, 87, 88, 90, 91, 92 and 93, drawn to a method of treating an infertility condition in a human or mammal by administering a prospective mother:

A) Antigen on the conceptus

B) Precursor activin plus plasmin

classified in Class 424, subclass 85.1, Class 424, subclass 520.

XXXI. Claims 94, drawn to a method of diagnosing infertility conditions in the male whether he has adequate levels of TGFβ, classified in Class 435, subclass 7.1.

XXXII. Claims 95, drawn to a method of diagnosing infertility in the female whether she has the capacity to activate TGFβ, classified in Class 435, subclass 7.72.

XXXIII. Claims 96-97, drawn to a composition of comprising of substantially purified TGFβ1, one or more paternal antigens, a pharmaceutically carrier and a vaginal gel, classified in Class 530, subclass 300, Class 514, subclass 944, Class 514, subclass 967.

XXXIV. Claims 96-97, drawn to a composition of comprising of substantially purified TGFβ2, one or more paternal antigens, a pharmaceutically carrier and a vaginal gel, classified in Class 530, subclass 300, Class 514, subclass 944, Class 514, subclass 967.

XXXV. Claims 96-97, drawn to a composition of comprising of substantially purified TGFβ3, one or more paternal antigens, a pharmaceutically carrier and a vaginal gel, classified in Class 530, subclass 300, Class 514, subclass 944, Class 514, subclass 967.

XXXVI. Claims 96-97, drawn to a composition of comprising of substantially purified TGFβ analog, one or more paternal antigens, a pharmaceutically carrier and a vaginal gel, Class 530, subclass 300, Class 514, subclass 944, Class 514, subclass 967.

XXXVII. Claims 96-97, drawn to a composition of comprising of substantially purified activin analog, one or more paternal antigens, a pharmaceutically carrier and a vaginal gel, Class 530, subclass 300, Class 514, subclass 944, Class 514, subclass 967.

XXXVIII. Claims 96-97, drawn to a composition of comprising of substantially purified precursor TGFβ1 plus platelets that actives TGFβ1, one or more paternal antigens, a pharmaceutically carrier and a vaginal gel, Class 530, subclass 300, Class 514, subclass 944, Class 514, subclass 967.

XXXIX. Claims 96-97, drawn to a composition of comprising of substantially purified precursor TGFβ2 plus platelets that actives TGFβ2, one or more paternal antigens, a pharmaceutically carrier and a vaginal gel, Class 530, subclass 300, Class 514, subclass 944, Class 514, subclass 967.

XL. Claims 96-97, drawn to a composition of comprising of substantially purified precursor TGFβ3 plus platelets that actives TGFβ3, one or more paternal antigens, a pharmaceutically carrier and a vaginal gel, Class 530, subclass 300, Class 514, subclass 944, Class 514, subclass 967.

XLI. Claims 96-97, drawn to a composition of comprising of substantially purified precursor TGFβ analog plus platelets that actives TGFβ analog, one or more paternal antigens, a pharmaceutically carrier and a vaginal gel, Class 530, subclass 300, Class 514, subclass 944, Class 514, subclass 967.

XLII. Claims 96-97, drawn to a composition of comprising of substantially purified precursor activin plus plasmin that actives activin, one or more paternal antigens, a pharmaceutically carrier and a vaginal gel, Class 530, subclass 300, Class 514, subclass 944, Class 514, subclass 967.

The inventions listed as Groups I-XLII above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The Invention of Group I was to have no special technical feature that defined the contribution over the prior art of U.S. Pat. 5,395,825, by Feinberg *et al.*, Chaouat *et al.* J. Immunol 134(3): 1594-8 (1985) and Toder *et al.* American J. of Reproductive Immunol (1991).

Feinberg *et al.* ('825) teach the methods of increasing the success rate of assisted reproduction by administering transforming growth factor beta (TGFβ) to female prior to, simultaneously with, or following introduction of ovum, sperm or coneptus to promote adhesiveness of trophoblast to the extra-cellular matrix, and thereby effectively enhances the implantation of the ovum or conceptus. (See entire document).

Feinberg *et al.* ('825) differs from the claimed invention by not disclosing the use of the paternal antigen in the same process.

Chaouat *et al.* teach immunizing infertile female mice with paternal MHC haplotype antigen can increase fetal protection from resorption (spontaneous abortion) and improve anti-abortive effects of pregnancy by suppressing maternal cell-mediated immunity.

Toder *et al.* teach immunization of infertile women who have high frequency of pregnancy loss due to spontaneous abortion with paternal or third party leukocyte antigen has resulted in more than 70 % of live birth.

Given the teaching of the references, the motivation to combine TGFβ and paternal antigens can arise from the expectation that the prior art elements will perform their expected functions to achieve successful immunotherapy for women with infertility. See Section MPEP 2144.07.

It was prima facie obvious to combine TGFβ and male antigens each of which is taught by prior art to be useful for treating infertility in women in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06. Therefore the inventions of Groups I-V, XI-XV, XXI-XXV, XXXI-XXXVII have been previously described.

Since Applicant's Inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single general inventive concept and lack unity of invention.

The Inventions are distinct, from each from the other because of the following reasons:

A. Groups (XXXIII-XLII) are different products of (different members of the TGFβ super-family and antigen).

In the instant case, they differ with respect to their structure, physiochemical properties, tissue specificity, as well as application. Therefore they are patentably distinct.

B. Groups (XXXIII-XLII and I-XXX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for making the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of making that product (M.P.E.P. § 806.05(h)).

In the instant case, the TGFβ protein can be used as the therapeutic methods as claimed or diagnostic/screening assays. Therefore, they are patentably distinct.

In the instant case, the TGFβ can be used as an agent to improve implantation in fertility therapy or to use as an immunosuppressive agent (i.e., to block NK activity) that has quite distinct outcome. Therefore, they are patentably distinct.

C. Groups I-XXXII are different methods.

In the instant case, the method of treating infertility versus diagnostic/screening assays. Therefore, they are patentably distinct.

6. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.
Patent Examiner
Art unit 1644
Technology Center 1600
Nov. 9, 2000

PHILLIP GAMBEL
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
11/13/00